

II. REMARKS

Formal Matters

Claims 1-8 and 10-22 are pending after entry of the amendments set forth herein.

Claims 1-18 were examined and were rejected. Claims 11 and 18 were objected to.

Claims 1, 10, 11, 15, 17, and 18 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendments to claims 1 and 17 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: claim 1: “living” individual: paragraph 0024; “aqueous” biological sample: paragraphs 0024 and 0091, and Example 1, paragraphs 00106-00109; “wherein a level ...”: paragraph 0026; and Example 1, paragraphs 00106-00109; claim 17: paragraphs 0066-0068. Accordingly, no new matter is added by these amendments. The amendments to claims 10, 11, 15, and 18 are merely editorial in nature. Accordingly, no new matter is added by these amendments.

Claim 9 is canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claim. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Claims 19-22 are added. Support for new claims 19-22 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: claim 19: Example 1, paragraphs 00106-00109; claim 20: paragraph 0087; claim 21: paragraph 0065; claim 22: paragraph 00103. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Objection to the drawing

The drawing was objected to. The Office Action stated that figure must not be enumerated since there is only one figure.

To support the objection, the Office Action cited 37 C.F.R. §1.84(u)(i). Applicants note that there does not appear to be a rule 1.84(u)(i). There is a rule 1.84(u), which relates to numbering of views; numbering of views is not applicable to instant Figure 1. Applicants are not aware of any rule that provides that where there is only one figure, it should not be called “Figure 1.” Applicants respectfully request that the Office point out exactly where such requirement might be set forth.

Objection to the specification

The specification was objected to. The Office Action stated that the brief description of the drawings should not refer to an enumerated figure as there is only one figure.

Applicants are not aware of any rule that provides that where there is only one figure, it should not be called "Figure 1." Applicants respectfully request that the Office point out exactly where such requirement might be set forth.

Claim Objections

Claims 11 and 18 were objected to.

Claim 11

The Office Action stated that the second "apoE" should be deleted.

Claim 11 is amended to delete the extra "apoE."

Claim 18

The Office Action stated that the second period at the end of the sentence should be deleted.

Claim 18 is amended to delete the extra period.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1-9 and 11-14 were rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. Applicants respectfully traverse the rejection.

Claim 1

The Office Action stated that claim 1 recites in the preamble a method for diagnosing Alzheimer's disease (AD); and stated that the body of the claim does not recite a step of diagnosing, or how the diagnosis was made.

Without conceding as to the correctness of this rejection, claim 1 is amended to recite "the method comprising detecting a level of carboxyl-terminal truncated apoE in an aqueous biological sample from the individual, wherein a level of carboxyl-terminal truncated apoE that is significantly higher than the level present in a normal control indicates that the individual has AD."

Claim 5

The Office Action stated that the phrase “the carboxyl-terminal truncated apoE comprises amino acids 244-260 of apoE” is not clear. The Office Action stated that it is not clear to what positions Applicant is referring. The Office Action stated that Applicant has not indicated whether the positions are determined starting from the amino terminus or the carboxyl terminus. Applicants respectfully traverse the rejection.

It is standard in the art to number amino acids starting from the amino terminus of a protein. As such, those skilled in the art would understand that the phrase “the carboxyl-terminal truncated apoE comprises amino acids 244-260 of apoE” means that the carboxyl-terminal truncated apoE comprises amino acids 244-260 of apoE, numbered from the amino terminus of apoE. As such, claim 5 need not be amended.

Conclusion as to the rejection under 35 U.S.C. §112, second paragraph

Applicants submit that the rejection of claims 1-9 and 11-14 under 35 U.S.C. § 112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under U.S.C. §103

Claims 1-18 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Roses et al. (U.S. Patent No. 5,508,167; “Roses”) in view of Huang et al. ((2001) *Proc. Natl. Acad. Sci. USA* 98:8838-8843; “Huang”).

The Office Action stated that: 1) Roses discloses a method for diagnosing AD, comprising detecting apolipoprotein E4 (apoE4) in a biological sample; 2) Roses teaches detecting apoE4 rather than carboxyl-terminal truncated apoE; and 3) Huang teaches that carboxyl-terminal truncated forms of apoE are found to be higher in patients with AD than in normal patients. The Office Action stated that it would have been obvious to modify the Roses method to diagnose AD in a patient by detecting carboxyl-terminal truncated apoE levels in the patient because Huang teaches the correlation between the presence of a higher level of carboxyl-terminal truncated apoE and the presence of AD. Applicants respectfully traverse the rejection.

The Office Action stated that “Roses et al. disclose the invention substantially as claimed.”

Office Action, page 4. It is not clear what is meant by this. As the Office Action correctly noted, Roses discusses “detecting apoE4 rather than carboxyl-terminal truncated apoE.” Office Action, page 5. As such, Roses does not “disclose the invention substantially as claimed.”

Roses discusses methods of diagnosing AD. Roses discusses detecting apolipoprotein E4. Roses neither discloses nor suggests detecting carboxyl-terminal truncated apolipoprotein E (apoE).

Huang does not cure the deficiency of Roses. Huang does not disclose or suggest that carboxyl-terminal truncated apoE would be present in a biological sample other than brain, and thus could be detected in a diagnostic test for AD. Huang states that carboxyl-terminal truncated apoE is present in brains of AD patients. Huang, page 8839, column 2, first paragraph under “Results.” Huang also states that carboxyl-terminal truncated apoE was detected in the lysates of transfected Neuro-2a cells expressing apoE3 or apoE4. Huang, page 8840, column 1, first paragraph. Huang further states that carboxyl-terminal truncated apoE is present in intracellular inclusions. Huang, page 8840, column 2; and Figure 2. Thus, from reading Huang, one skilled in the art would not conclude that carboxyl-terminal truncated apoE would be present outside the brain, or in an aqueous biological sample that would normally be obtained from a living individual. As such, Roses, alone or in combination with Huang, cannot render instant claims 1-18 obvious.

Conclusion as to the rejection under 35 U.S.C. §103(a)

Applicants submit that the rejection of claims 1-18 rejected under 35 U.S.C. 103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-281.

Respectfully submitted,
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